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Attorney Docket No. 12730-11
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Thomas A. Osborne et al.	
Serial No. 10/642,513	Examiner: William H. Matthews
Filing Date: August 15, 2003	Group Art Unit No.: 3774
For Stent and Method of Forming a Stent with Integral Barbs	

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

By filing this Appeal Brief in accordance with 37 C.F.R. § 41.37, Appellant respectfully requests review of the grounds of rejection in the present application.

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REAL PARTY IN INTEREST

The real party in interest is Cook Incorporated, the assignee of record in the present application.

RELATED APPEALS AND INTERFERENCES

The appellant is not aware of any prior or pending appeals, judicial proceedings or interferences that may be related to, directly affect, or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-44 are cancelled.

Claims 47, 51, 52, 54-57, 59, 63, and 64 are withdrawn from consideration.

Claims 45, 46, 48-50, 53, 58, and 60-62 are rejected. The rejection of these claims is being appealed.

STATUS OF AMENDMENTS

Appellant filed a response to the final Office action dated July 16, 2007 on September 14, 2007. The response contained no amendments to the claims. According to an Advisory Action dated October 9, 2007, the Examiner has considered the reply.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 45 is directed to a barbed stent for deployment within the body of a patient, as shown for example in Figures 87-92. The barbed stent 355 includes a wire 352 having at least one integrally formed barb 357 configured to engage tissue adjacent to the stent. The wire 352 includes at least one bend connecting to at least two struts such that the barb 357 points in a predetermined direction at an angle relative to the longitudinal axis 359 of the stent 355, as shown for example in Figures 90b and 91. (¶215) The barb 357 is unbent with respect to the wire 352 and is free from weakening due to bending. (¶18, ¶205)

Dependent claim 46 recites that the wire 322 may have a zig zag shape, as shown for example in Figures 86a and 86b (¶208). Such a zig zag shape of the barbed stent is also shown in Figures 90a and 90b (¶215) and in Figure 91 (¶217).

Dependent claim 48 recites that the barb 357 may point in a direction at a generally transverse angle relative to the longitudinal axis 359 of the stent 355, as shown for example in Figures 90b and 91 (¶215).

Dependent claim 49 recites that the barb 314 is positioned on the bend 326 of the wire 322, as shown for example in Figures 86b and 91 (¶208).

Dependent claim 50 recites that each bend includes at least one barb 357 positioned thereon, as shown for example in Figures 90a, 90b and 91. (¶215)

Dependent claim 53 recites that the stent is adjacent to a proximal end of an endoluminal prosthesis, as shown for example in Figure 91. (¶119)

Independent claim 58 is directed to an endoluminal prosthesis including a substantially cannular body with proximal and distal ends. Referring to Figure 91, the stent 360 is affixed to the substantially cannular body 362 near the proximal end (¶119), and the stent 360 includes a wire having at least one integrally formed barb 364 that has not been attached to the stent 360 during the manufacturing process and is configured to engage tissue adjacent the stent 360. The wire includes at least one bend connecting to at least two struts such that the at least one barb 364 points in a predetermined direction at an angle relative to a longitudinal axis 366 of the stent 360

(¶215-¶217). The barb 364 is unbent with respect to the wire and is free of weakening due to bending (¶205).

Dependent claim 60 recites that the stent 360 is in a zigzag shape, as shown for example in Figure 91 (¶217).

Dependent claim 61 recites that the barb 314 is positioned on the at least one bend 326 and/or at least one of the at least two struts 328, as shown in Figures 86a, 86b, and 91 (¶208).

Dependent claim 62 recites that the barb 357, 374 points in a direction at one of an acute angle and a generally transverse angle relative to the longitudinal axis 359, 376 of the stent 355, 372, as shown for example in Figures 90b, 91, and 92 (¶215 and ¶218).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 45, 46, 48-50, 53, 58, and 60-62 are unpatentable under 35 U.S.C. § 102(b) over U.S. Patent 5,800,526 (Anderson et al.).

ARGUMENTS

Rejection of Claims 45, 46, 48-50, 53, 58, and 60-62 Under 35 U.S.C. § 102(b) over U.S. Patent 5,800,526 (Anderson et al.)

Claims 45, 46, 48-50, 53, 58, and 60-62 are currently pending and are rejected under 35 USC § 102(b) as anticipated by U.S. Patent No. 5,800,526 ("Anderson"). Appellant respectfully submits that the Examiner has failed to establish a *prima facie* case of anticipation.

Independent claims 45 and 58 are directed to stents comprising wires having at least one integrally-formed barb that points in a predetermined direction at an angle relative to a longitudinal axis of the stent. The integrally-formed (*i.e.*, integral) barb has not been attached to the wire during the manufacturing process. The integral barb is unbent with respect to the wire and is free of weakening due to bending.

Anderson describes only two ways to form a barb on a wire. First, the "barbs can be formed independently of the stent and subsequently attached to it by welding, brazing or another process with the equivalent effect." (col. 6, lines 64-67) Such a structure is clearly a non-integral barb and does not anticipate the claimed invention.

Anderson also describes barbs formed from a flat sheet of material or a tube "by chemically etching, laser cutting, or electronic discharge machining (EDM), and the like." (*e.g.*, col. 6, lines 60-63 or col. 8, lines 52-54). Anderson discloses throughout the specification and in the drawings that such barbs are oriented in alignment with the longitudinal axis of the stent and not at an angle relative to a longitudinal axis of the stent, as recited in the rejected claims. "Each of the barbs also preferably faces in alignment with the common longitudinal axis when the multi-anchor stent is in an unexpanded configuration." (col. 4, lines 13-16; col. 7, lines 47-50) These unexpanded structures (*e.g.*, Figs. 1-5 and 15) clearly do not anticipate the pending claims.

Anderson's expanded structures also do not anticipate the claimed invention. In particular, the expansion of Anderson's stents results in 1) a barb that is bent with respect to the wire and weakened due to bending; and/or 2) a barb that points in an arbitrary, rather than a predetermined, direction. Anderson does not expressly or

inherently disclose an expanded stent including at least one integrally-formed, unbent barb that points in a predetermined direction with respect to the longitudinal axis of the stent.

The Examiner asserted in the Final Office Action dated July 16, 2007 that Anderson's barbs are not bent during expansion of the stent. This contention, however, is clearly refuted by the Anderson specification. Anderson teaches a balloon-expandable stent that is necessarily plastically deformed upon application of an expansion force, as described at col. 7, lines 32-56. Anderson teaches, in reference to Figure 2, which shows barbs 20 extending from valleys 18 of the cylindrical elements of the stent 10, that "the peaks and valleys of each band deform radially with substantial uniformity upon application of an expansion force." The Examiner has provided no evidence that the barbs extending from the valleys of Anderson's stent avoid the recited radial deformation; to the contrary, Anderson teaches that the deformation is a "uniform radial expansion" (col. 8, line 17) across the entire stent structure.

The Examiner merely posits that "expansion or rotation of the stent struts does not require bending of the barbs." He has provided neither objective evidence nor cogent technical reasoning to support the assertion that unbent barbs are necessarily present in Anderson's expanded stent.

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (Emphasis in original)

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. (MPEP 2112(IV))

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by person of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (Emphasis added)

As described above, Anderson expressly teaches that radial deformation of the stent occurs uniformly over the entire stent structure upon application of an expansion force. Furthermore, in col. 9, lines 19-25, Anderson expressly teaches bending of the barbs during expansion. In particular, he discloses the use of a step etching process during forming to enhance the bending or distortion of the barbs when the stent is subjected to an expansion force. He states that "by using step etching in the areas of the attachment elements or barbs 20 of Figure 3, it is possible to remove portions of material so that the barbs will bend outwardly when the stent is expanded. In other words…upon radial expansion of the stent, areas having less material will have a tendency to bend or distort." Emphasis added.

Besides Anderson's failure to disclose, either expressly or inherently, an expanded stent including integrally-formed unbent barbs, the reference also fails to teach an expanded stent with barbs pointing in a predetermined direction, as recited by the claims.

As explained in Appellant's specification, "it is preferable to orient the barbs 314 properly so that they will point in the desired direction in relation to the longitudinal axis of the final stent shape." ¶205. The proper orientation is important to "ensure[] that the barbs 'catch' and engage the adjacent tissue." ¶206. Thus, a predetermined orientation of the barb in the expanded configuration, as opposed to an arbitrary or unknown orientation, is an important aspect of the claimed invention.

In contrast, Anderson's balloon expandable stent may be expanded "to any number of larger diameters." (col. 7, lines 41-44). Moreover, "[t]he special expansion characteristics of the stent of the invention [allows] any portion of the stent that extends distally or proximally of the graft to continue to expand even when the graft has achieved its maximum cross-sectional dimension . . . " (col. 8, lines 25-31). Accordingly, the barbs of Anderson's stent may be radially deformed to any number of configurations and thus oriented in any number of directions. The barbs of such a stent do not point in a predetermined direction, as required by the claimed invention. Indeed, Anderson disparages stents where "exact placement of an anchoring stent . . . [is] critical for properly securing the stent," and provides a stent with "a plurality of barbs

throughout the entire circumference of the stent . . . so that exact placement of the anchors is less critical." (col. 3, lines 5-8; col. 3, lines 33-39)

In the Advisory Action dated October 9, 2007, the Examiner cited column 12, lines 60-65 of Anderson as disclosing a predetermined direction of the barbs. This section of Anderson teaches that "multiple barbs 142 also can be formed on the outer edges of the peaks and valleys of the cylindrical rings so that the barbs will be directed outwardly when the stent is expanded, to allow the stent to better grip whatever portion of the vasculature comes into contact with the stent." Having barbs directed outwardly in some arbitrary configuration and at some random angle depending on the manner and extent of the expansion does not constitute a disclosure of barbs pointing in a pre-determined direction, as recited in the claims.

In the Final Office Action dated July 16, 2007, the Examiner asserted that Figures 16 and 17 "describe additional embodiments in which integral barbs are formed outward (figure 16) or that point outward upon expansion (figure 17)." Anderson teaches in regard to Figure 17 that "multiple barbs 142 also can be formed on the outer edges of the peaks and valleys of the cylindrical rings so that the barbs will be directed outwardly when the stent is expanded." As noted above, barbs having a deployed orientation that depends on the extent of the expansion of the stent do not satisfy the claim limitation of pointing in a pre-determined direction. In regard to figure 16, Anderson says only that barbs can be "formed in the surface of the cylindrical elements . . . to provide a sandpaper effect of raised, pointed, directional bumps of the surface of the stent." As explained above, Anderson describes only two ways to form a barb: 1) welding, brazing, and the like; and 2) chemically etching, laser cutting, or EDM. The first method results in non-integral barbs, and the second method results in barbs that are bent and weakened and/or barbs that do not point in a predetermined direction at an angle relative to a longitudinal axis of the expanded stent. Accordingly, neither of these figures teaches or discloses all of the features recited in claims 45 and 58.

Because Anderson does not teach or disclose, expressly or implicitly, each and every limitation of independent claims 45 and 58, it cannot anticipate these claims or any claims depending therefrom. The Examiner has failed to make a *prima facie* case of anticipation, and therefore the rejection of claims 45, 46, 48-50, 53, 58, and 60-62 is

improper. Appellant respectfully requests that the Examiner's decision be REVERSED and these claims be allowed to pass to issuance.

Respectfully submitted,

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CLAIMS APPENDIX

1-44. (Cancelled)

45. (Previously presented) A barbed stent for deployment within the body of a patient, comprising:

a wire having at least one integrally formed barb that has not been attached to the wire during the manufacturing process, configured to engage tissue adjacent the stent;

wherein the wire comprises at least one bend connecting to at least two struts such that the at least one barb points in a predetermined direction at an angle relative to a longitudinal axis of the stent, wherein the at least one barb is unbent with respect to the wire and is free of weakening due to bending.

46. (Previously presented) The stent of claim 45, wherein the wire is in a zigzag shape.

47. (Withdrawn) The stent of claim 45, wherein the at least one barb points in a direction at an acute angle relative to the longitudinal axis of the stent.

48. (Previously presented) The stent of claim 45, wherein the at least one barb points in a direction at a generally transverse angle relative to the longitudinal axis of the stent.

49. (Previously presented) The stent of claim 45, wherein the at least one barb is positioned on the at least one bend.

50. (Previously presented) The stent of claim 45, wherein each of the at least one bend comprises at least one barb positioned thereon.

51. (Withdrawn) The stent of claim 45, wherein the at least one barb is positioned on at least one of the at least two struts.

52. (Withdrawn) The stent of claim 45, wherein each of the at least two struts comprises at least one barb positioned thereon.

53. (Previously presented) The stent of claim 45, wherein the stent is adjacent a proximal end of an endoluminal prosthesis.

54. (Withdrawn) The stent of claim 53, wherein the at least two struts extend away from the proximal end of the endoluminal prosthesis in a proximal direction.

55. (Withdrawn) The stent of claim 54, wherein the endoluminal prosthesis is adapted to be deployed at least partially within the aorta, so that the stent extends at least partially above a renal artery when the prosthesis is implanted.

56. (Withdrawn) The stent of claim 53, wherein the prosthesis is a bifurcated aortic prosthesis.

57. (Withdrawn) The stent of claim 45:

wherein the wire is in a zigzag shape and the at least one barb points in a direction at one of an acute angle and a generally transverse angle relative to the longitudinal axis of the stent, the at least one barb being positioned on one of:

a) the at least one bend; and

b) at least one of the at least two struts; and

wherein the stent is adjacent a proximal end of a bifurcated aortic endoluminal prosthesis, the at least two struts of the stent extending away from the proximal end of the endoluminal prosthesis in a proximal direction, the endoluminal prosthesis being adapted to be deployed at least partially within the aorta, so that the stent extends at least partially above a renal artery when the prosthesis is implanted.

58. (Previously presented) An endoluminal prosthesis comprising:

a substantially cannular body having proximal and distal ends; and

a stent affixed to the substantially cannular body near the proximal end, the stent comprising a wire having at least one integrally formed barb that has not been attached to the wire during the manufacturing process, configured to engage tissue adjacent the stent;

wherein the wire comprises at least one bend connecting to at least two struts such that the at least one barb points in a predetermined direction at an angle relative to a longitudinal axis of the stent, wherein the at least one barb is unbent with respect to the wire and is free of weakening due to bending.

59. (Withdrawn) The prosthesis of claim 58, wherein the substantially cannular body is bifurcated.

60. (Previously presented) The prosthesis of claim 58, wherein the stent is in a zigzag shape.

61. (Previously presented) The prosthesis of claim 58, wherein the at least one barb is positioned on one of:

a) the at least one bend; and

b) at least one of the at least two struts.

62. (Previously presented) The prosthesis of claim 58, wherein the at least one barb points in a direction at one of an acute angle and a generally transverse angle relative to the longitudinal axis of the stent.

63. (Withdrawn) The prosthesis of claim 58, wherein at least a portion of the stent extends proximally away from the proximal end of the cannular body.

64. (Withdrawn) The prosthesis of claim 58:

wherein the stent is in a zigzag shape and the at least one barb points in a direction at one of an acute angle and a generally transverse angle relative to the longitudinal axis of the stent, the at least one barb being positioned on one of:

a) the at least one bend; and

b) at least one of the at least two struts; and

wherein the substantially cannular body is bifurcated and at least a portion of the stent extends proximally away from the proximal end of the cannular body.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.